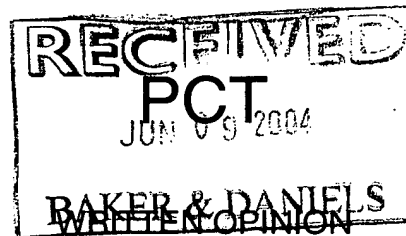


PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

NIEWYK, Anthony
BAKER & DANIELS
111 East Wayne Street
Suite 800
Fort Wayne, Indiana 46802
ETATS-UNIS D'AMERIQUE



(PCT Rule 66)

Date of mailing (day/month/year) 03.06.2004	
Applicant's or agent's file reference NGP0024-021	REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/GB 03/04174	International filing date (day/month/year) 25.09.2003
Priority date (day/month/year) 25.09.2002	
International Patent Classification (IPC) or both national classification and IPC A61M5/32, A61M5/32	
Applicant NMT GROUP PLC et al.	

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input type="checkbox"/>	Certain observations on the international application

REPLY DUE: *Resp to written opinion*
9-3-04
DOCKET 1 ☒ DOCKET 2 ☒

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25.01.2005

Name and mailing address of the international preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epnu d

Authorized Officer

Ehrsam, F

Formalities officer (incl. extension of time limits)

Schmidbauer, A



I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-9 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-21
Inventive step (IS)	Claims	1-21
Industrial applicability (IA)	Claims	

2. Citations and explanations**see separate sheet**

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/GB 03/04174

The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: WO 03/051436 A (MAGGIONI TARCISIO ;TECNEDIL SRL (IT)) 26 June 2003 (2003-06-26)
- D2: WO 02/068025 A (MAXXON INC) 6 September 2002 (2002-09-06)
- D3: US-A-5 221 262 (KITE JOHN P) 22 June 1993 (1993-06-22)
- D4: US-A-5 385 551 (SHAW THOMAS J) 31 January 1995 (1995-01-31)
- D5: FR-A-1 006 260 (DORMOY JULES-MARIE-JOSEPH) 21 April 1952 (1952-04-21)
- D6: US-A-6 015 438 (SHAW THOMAS J) 18 January 2000 (2000-01-18)
- D7: WO 02/087669 A (NMT GROUP PLC ;TARGELL JOHN (GB)) 7 November 2002 (2002-11-07)

See point V of the report:

1. The present application does not meet the requirements of Article 33 (2) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33 (2) PCT. Indeed, document D2 discloses all the features of claim 1, in particular figure 4 shows a plastic portion which is not in contact with the prefilled contents of the syringe, see in particular figure 4, the element referenced as 44 and covered by the seal (42) of the piston (20). The same objection applies for document D5 and the intermediate documents D1 and D7 in particular the figures which are showing a plastic portion which is not in contact with the prefilled contents of the syringe.
2. Furthermore, the subject-matter of claims 1-21 lacks inventive step (Art. 33 (3) PCT.
A pre-filled hypodermic syringe is already known from the document D3, where a plastic portion is not in contact with the prefilled contents of the syringe, see figure 4 and abstract.
The sole difference of the subject-matter of claim 1 over D3 is that the piston of D3 is not provided by a piston member.
However, if the skilled man would wish to improve the ejection of the needle, he would have used the known system as disclosed in D4, col. 10, line 47-66 and figures 4 and 5. One skilled in the art would have thus arrived at the syringe of the present invention.

The subject-matter of the above mentioned claims does therefore not appear to involve an inventive step.

3. The description must be brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b)).
4. To meet the requirements of Rules 6 3 b) the independent claim should be properly cast in a two part form, with those features which in combination are part of the nearest prior art being placed in the first part.
5. To meet the requirements of Rule 5.1 a vi, the cited documents should be identified in the description and the relevant background art therein is to be indicated.
6. The features of the claim/s are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
7. It is also mentioned that although claims 1 and 2 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1 and 2 do not meet the requirements of Rule 6 PCT.